K010553

JUN 1 8 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted by:

Janet Connolly, RAC
Regulatory Affairs Specialist
Abbott Laboratories, MediSense Products
4A Crosby Drive
Bedford, MA 01730-6230

Device Name: Precision Xtra/MediSense Optium Blood Glucose Test Strip with MediSense TrueMeasure™Technology

Common Name: Self-Monitoring Blood Glucose Test Strip

Classification: Glucose Test System
Class II per 21 CFR 862.1345

Predicate Device: Precision Xtra Advanced Diabetes Management System K983504 which utilizes the blood glucose test strip cleared as Precision QID Blood Glucose Test Strip K971812.

Description: The modified Precision Xtra Blood Glucose Test Strip for blood glucose testing with the Precision Xtra/Optium Blood Glucose meter utilizes amperometric biosensor technology to generate a current. The size of the current is proportional to the amount of glucose present in the sample, providing a quantitative measure of glucose in whole blood and control solutions.

Intended Use: The Precision Xtra Blood Glucose Test Strip is intended for in vitro diagnostic use for the quantitative measurement of glucose in fresh capillary whole blood. The system is for home use.

Comparison to Predicate Device: The modified Precision Xtra Blood Glucose Test Strip has equivalent technological characteristics as the Precision Xtra Advanced Diabetes Management System K983504 which uses the Precision QID Blood Glucose Test Strip K971812.

Performance Studies: The performance of the modified Precision Xtra Blood Glucose Test Strip was studied in the laboratory and in clinical settings by healthcare professionals and lay users. The studies demonstrated that lay users could obtain blood glucose results that are substantially equivalent to the current methods for blood glucose measurements, which include the predicate device listed above.

Conclusion:

Results of laboratory and clinical testing demonstrate that the performance of the modified Precision Xtra Blood Glucose Test Strip, when used according to the intended use stated above, is acceptable and comparable to the performance of the previously mentioned predicate device for blood glucose testing. In addition, results of clinical performance testing demonstrate that trained operators and lay users obtain equivalent whole blood glucose results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Janet Connolly, RAC
Regulatory Affairs Specialist
Abbott Laboratories, MediSense Products
4A Crosby Drive
Bedford, MA 01730-1402

Re: 510(k) Number: K010553
Trade/Device Name: Precision Xtra/MediSense Optium Blood Glucose Test Strips with MediSense TrueMeasure™ Technology
Regulation Number: 862.1345
Regulatory Class: II
Product Code: NBW, LFR
Dated: February 23, 2001
Received: February 26, 2001

Dear Ms. Connolly:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE FORM

510(k) Number (if known): K010553

Device Name: Precision Xtra/MediSense Optium Blood Glucose Test Strips with MediSense TrueMeasure™ Technology

Indications For Use:

The Precision Xtra/MediSense Optium Blood Glucose Test Strip is intended for in vitro diagnostic use for the quantitative measurement of glucose in fresh capillary whole blood. The test strip is for home (lay user) use.

Fred Lacy

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010553

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The-Counter Use ✓
(Per 21 CFR 801.108)